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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,650	02/12/2001	Robert John D'Amato	43170-253692 (05213-0493)	2466

7590 01/27/2003

Suzanne Seavello Shope
KILPATRICK STOCKTON LLP
Suite 2800
1100 Peachtree Street
Atlanta, GA 30309-4530

EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/780,650

Applicant(s)

D'AMATO ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 26-42 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- ☐ Interview Summary (PTO-413) Paper No(s) ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

u 2. **The objection to the amendment filed May 23, 2002 under 35 USC 132 is maintained.**

Applicant argues that the application as filed encompasses all of the claimed diseases because each arises from undesired angiogenesis and is characterized by abnormal cell mitosis. Applicant also argues that the specification need not disclose what is well known to those skilled in the art and already available to the public. Applicant's argument was considered but not persuasive for the following reasons.

Applicant cannot add to the specification that which was not mentioned in the application as originally filed. According to the MPEP § 706.03(o), new matter includes addition of specifics or even omission of a step from a method (see MPEP 706.03(o)). The instant amendment seeks to add specific diseases not disclosed in the original application and, thus, is objected to for addition of new matter. It is suggested that the amendment be limited to diseases originally disclosed by the present specification.

In response to applicant's argument of what is known in the art, it should be noted that the prior art does not teach the use of the claimed compound in treatment of all of the diseases recited by the instant amendment and, thus, it was not known in the

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art. The fact that other compounds that inhibit angiogenesis are useful in treatment of certain diseases does not imply that all compounds that inhibit angiogenesis would be useful in said diseases.

For these reasons and those given in Paper No. 9, the objection to the amendment filed May 23, 2002 under 35 USC 132 is maintained.

Claim Rejections - 35 USC § 112

u) 3. The rejection of claims ~~27~~, ~~32~~, ~~34~~ and ~~40-42~~ under 35 USC 112, first paragraph is maintained.

Applicant argues the specification (a) as originally filed conveys to the skilled artisan in the art that applicant had possession of the claimed invention and (b) need not disclose what is well known to those skilled in the art and already available to the public. Applicant's argument was considered but not persuasive for the following reasons.

As stated above in #2, new matter includes addition of specifics after a broader original disclosure (see MPEP § 706.03(o)). The instant claims recite or include diseases, such as osteoporosis or menopause, not disclosed by the originally filed specification.

The prior art also does not disclose the claimed compound in treatment of all of the claimed diseases. As discussed above in #2, the fact that another prior art compound having anti-angiogenic is known to treat a certain disease does not imply that any anti-angiogenic compound would also be useful in treating said disease. For

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example, the art teaches numerous anti-tumor agents, however, there is not one single anti-tumor compound known in the art that is useful in treatment of all tumors.

For these reasons and those given in Paper No. 9, the rejection of claims 27, 32, 34 and 40-42 under 35 USC 112, first paragraph is maintained.

4. The rejection of claim 41 under 35 USC 112, second paragraph is withdrawn.

Double Patenting

5. The provisional rejection of claims 26-42 under the judicially created doctrine of obviousness-type double patenting over claims 15 and 19 of copending Application No. 09/899,702 is maintained.

Applicant states this rejection will be addressed when the 09/899,702 application issues. Said application has not issued and, thus, the provisional rejection of claims 26-42 under the judicially created doctrine of obviousness-type double patenting over claims 15 and 19 of copending Application No. 09/899,702 is maintained.

6. The rejection of claims 26-42 under the judicially created doctrine of obviousness-type double patenting over claims 1 and 2 of US Patent No. 5,504,074 is withdrawn.

7. The rejection of claims 26-42 under the judicially created doctrine of obviousness-type double patenting over claims 1 and 6 of US Patent No. 5,661,143 is withdrawn.

8. The rejection of claims 27-42 under the judicially created doctrine of obviousness-type double patenting over claims 1-3 of US Patent No. 5,643,900 is withdrawn.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

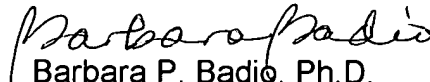
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Telephone Inquiry

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
January 27, 2003